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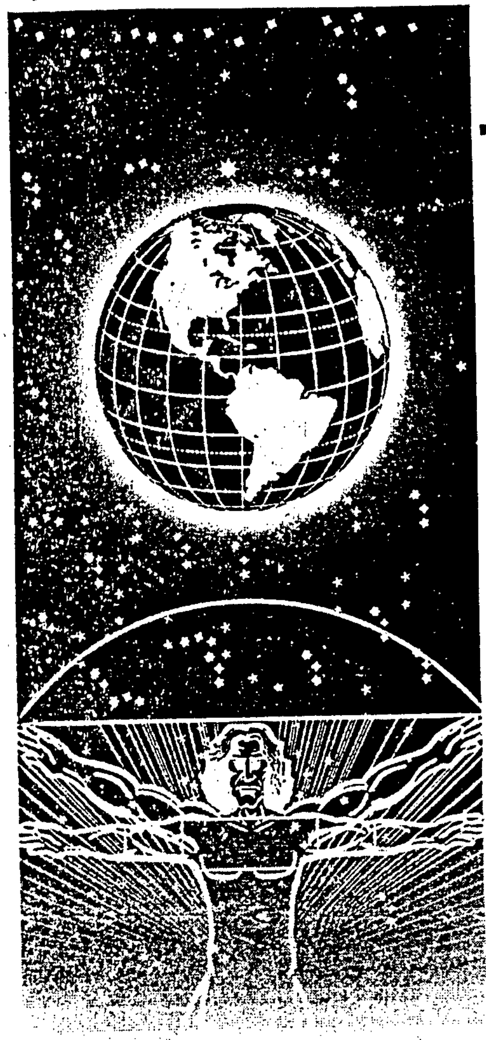

UNITED STATES AIR FORCE RESEARCH LABORATORY

TESTING AND EVALUATION OF THE NEONATAL/PEDIATRIC ECMO TRANSPORT SYSTEM, MODEL WHMC-96.

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May 2000

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NOTICES

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The Neonatal/Pediatric ECMO Transport System, Model WHMC-96 consists of multiple components and a transport gurney. This system provides life-sustaining oxygen to neonatal and pediatric patients, bypassing damaged or failed respiratory tissue. The system is made up of a CDI, 3M Healthcare CDI 400 Extracorporeal Blood Gas Monitoring System, a modified Tripplite® Isobar Model 1B-4 Noise Filter and Transient Voltage Surge Suppressor, a Seabrook Model SMS-3000 ECMO-Temp Blood Warming Unit, a Stöckert Shiley Multiflow Roller Pump Module, 10H Series, Model 10-10-00, a Topaz Uninterruptible Power Supply, Model 84126-01, a Venous Controller/Blood Pump Regulator, and a Neonatal/Pediatric ECMO Transport Gurney, Model WHMC-96.

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The author would like to thank LCDR (Dr.) Jeff Butler and Major (Dr.) Dan Beihl, Project Directors, ECMO Clinical Service, Wilford Hall Medical Center (WHMC) who served as technical advisors during the development and evaluation of Neonatal/ Pediatric ECMO Transport System, Model WHMC-96. I especially would like to thank TSgt Mike Smith, Aircraft Metals Technology Craftsman assigned to AFRL/HEPM, Fabrication and Engineering section who fabricated the Neonatal/Pediatric ECMO Transport Gurney, Model WHMC-96. I would also like to thank:

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TESTING AND EVALUATION OF THE
NEONATAL/PEDIATRIC ECMO
TRANSPORT SYSTEM, MODEL WHMC-96

BACKGROUND

HSD/YAM requested that Aeromedical Research, on behalf of the of Wilford Hall Medical Center's Extracorporal Membrane Oxygenation (ECMO) team, evaluate new ECMO equipment for use on board USAF aeromedical evacuation aircraft. In addition, they requested a transport gurney be developed to accommodate patients ranging from neonates up to 60 kg pediatric. All of the medical equipment required to support an ECMO transport would be positioned and secured on the transport gurney. ECMO is a heart-lung bypass technique currently used for 34 week gestation infants through adults with life threatening cardiac or respiratory failure. The previously approved Aerovac ECMO system can only accommodate infants. The newer equipment will accommodate neonate patients, as well as older/larger pediatric patients up to 60 kg.

The ECMO components submitted for evaluation consisted of the CDI, 3M Health Care CDI 400 Extracorporeal Blood Gas Monitoring System; Seabrook Model SMS-3000 ECMO-Temp Blood Warming Unit; Stöckert Shiley Multiflow Roller Pump Module 10H Series Model 10-10-00. Other ECMO components previously approved for aeromedical evacuation submitted for placement on the gurney were the Topaz Uniterruptible Power Supply and Venous Controller/Blood Pump Regulator (referred to as a "bladder box"). A modified Tripplite Isobar Model IB-4 Noise Filter and Transient Voltage Surge Suppresser was added to the inventory of ECMO equipment. This last subcomponent was required to support use of the roller pump and blood warming unit. These system components and transport gurney are designated as the Neonatal/Pediatric ECMO Transport System, Model WHMC-96. An incubator was not included as a component because a 20" X 40" plexiglas bassinet secures to the top of the transport gurney. After all the new components underwent the airworthiness testing protocols, the transport gurney was designed and fabricated.

A transport gurney prototype was designed and fabricated. The ECMO directors viewed the prototype and requested a design modification. The design was modified to increase the space on the center equipment shelf to accommodate previously approved medical equipment. All the ECMO equipment listed above and a Protocol Propaq 106EL were installed on the gurney. The ECMO directors approved the prototype and the final product was fabricated by AFRL/HEPM. Throughout this report, the term Equipment Under Test (EUT) refers to the Neonatal/Pediatric ECMO Transport System, Model WHMC-96 (Figure 1).

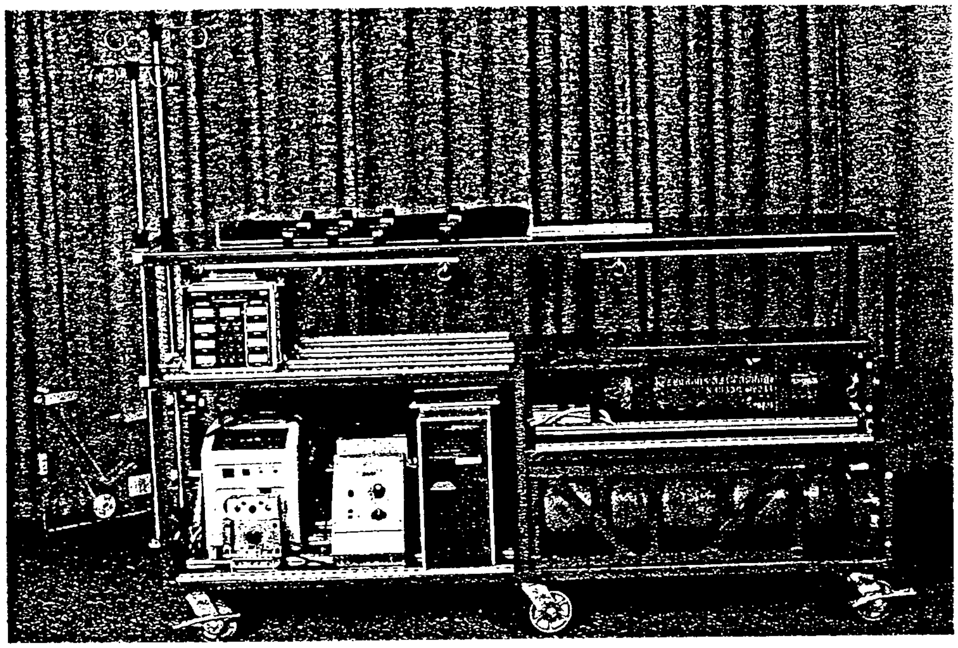

Figure 1. Neonatal/Pediatric ECMO Transport System

DESCRIPTION

The following is a description of all the components of the Neonatal/Pediatric ECMO Transport System, Model WHMC-96:

CDI, 3M Health Care CDI 400 Extracorporeal Blood Gas Monitoring System

The CDI 400 provides continuous, on-line monitoring of extracorporeal pH, PCO_2, PO_2, temperature, calculated arterial base excess (BE) or bicarbonate (HCO_3), and venous oxygen saturation (S_vO_2). It is intended for continuous monitoring blood gas and pH during cardiopulmonary bypass procedures. The CDI 400 utilizes a microprocessor based monitor and optical fluorescence technology. The fiberoptic cable assemblies (one venous and one arterial) connect the monitor to a disposable sensor and flow-through cell inserted into the extracorporeal circuit. Light pulses, originating from a flash lamp located in the monitor, pass through optical filters so light pulses of a specific frequency are transmitted down the fiberoptic bundles to the microsensors. The microsensors are composed of fluorescent chemicals which emit light in response to the stimulating pulses. The intensity of this emitted light depends upon the concentration of oxygen, carbon dioxide, and hydrogen ions passing through the gas and ion permeable membrane. The light emitted by the fluorescent microsensors is returned to the monitor through receiving optical fibers in the fiberoptic bundle. A filter is used to isolate the specific frequencies of interest from the returning light spectrum for measurement by a light detector. The output signal of the detector is converted by the microprocessor to a numerical readout in millimeters of mercury (mm Hg), kilopascals (kPa), or pH units which is displayed on the face of the monitor. The CDI 400 also displays calculated values for either the arterial base excess (mEq/L) or arterial bicarbonate concentration (mEq/L) and venous hemoglobin O_2 saturation (%). The CDI 400 operates from 115 VAC / 60 Hz power and weighs 16.3 lbs. The dimensions are 9.5 in. H. X 9.75 in. W. X 9 in. D.

Modified Tripplite® Isobar Model IB-4 Noise Filter and Transient Voltage Surge Suppresser
The modified IB-4 provides noise filtering and transient voltage surge suppression and reduces conducted emissions in excess of MIL-STD-461D. See Appendix II for modification procedures.

Seabrook Model SMS-3000 ECMO-Temp Blood Warming Unit (2)
The SMS-3000 provides a flow of temperature controlled water to a heat exchanger. This heat exchanger is connected in the blood flow path in series between the oxygenator and the patient during an ECMO procedure. It provides a means for warming and controlling blood temperature prior to and during perfusion. The SMS-3000 consists of a plastic reservoir for holding distilled water; a float switch to indicate low water level; a pump for circulating water through an external heat exchanger; a heating element to warm the water; a microprocessor-based electronic control to regulate water temperature; two independent back-up high limit devices to protect the patient and the unit; a water flow indicator to provide visual assurance of proper water flow; two connecting hoses for attachment of the heat exchanger; and a fan for removing heat generated within the unit enclosure. A phone jack marked "Blood Probe" allows connection of a 400 series-type thermistor probe for monitoring and/or controlling blood temperature. The control panel offers two modes of operation: "Water Temp" and "Blood Temp". In the " Water Temp" mode, the operator selects the desired water temperature setpoint and the SMS-3000 maintains the water at that temperature. In the "Blood Temp" mode, the operator selects the desired blood temperature as measured by the remote probe, and the SMS-3000 regulates the water temperature to maintain the blood temperature at the setpoint. The "Blood Temp" mode was not evaluated because the ECMO team did not require this mode. Audible and visual alarms indicate "Add Water", "Under Setpoint", "Over Setpoint", and "High Limit". Digital displays indicate water temperature, setpoint, and blood temperature (when a probe is connected), in degrees centigrade. The SMS-3000 operates from 115 VAC / 60 Hz power and weighs 24 lbs (dry). The dimensions are 9.75 in. W. X 14 in. H. X 11 in. D.

Stöckert Shiley Multiflow Roller Pump Module, 10H Series, Model 10-10-00 (3)
The Model 10-10-00 roller pump is a 115 VAC/60 Hz precision peristaltic pump, which is the principle component of the Neonatal/Pediatric ECMO Transport System. The Model 10-10-00 roller pump as installed on the Neonatal/ Pediatric ECMO Transport Gurney includes a Venous Controller, often referred to as a "bladder box", and a Topaz Uniterruptible Power Supply which powers the EUT if AC power is interrupted. The Model 10-10-00 roller pump is plugged into the bladder box. The bladder box is placed in the "Run" mode, and plugged into the modified Tripplite Isobar. The modified Tripplite Isobar is plugged into the Topaz, and the Topaz is plugged into aircraft 115 VAC, 60 Hz power. An example of this sequence is listed below:
Roller Pump → Bladder box → Modified Tripplite Isobar → Topaz UPS → 115 VAC/60 Hz power

The Model 10-10-00 roller pump accommodates a wide range of flow rates using different tubing diameters together with different size tubing inserts available for the monitor. It is capable of displaying both revolutions per minute (RPM) and flow rates in liters per minute (LPM). Only LPM's should be displayed during an ECMO transport. The Model 10-10-00 roller pump weighs 55 lbs and dimensions are 7.1 in. W. X 11.3 in. H. X 18.3 in. D.

Topaz Uniterruptible Power Supply (UPS), Model 84126-01

The Topaz UPS provides portable operating power, 115 VAC/60 Hz, to the multiflow roller pump and blood warming unit, which do not have internal battery power for ground transport to and from the aircraft. Once loaded on board the aircraft, the Topaz UPS is connected to the aircraft's 115 VAC/60 Hz power supply. The Topaz UPS weighs 90 lbs and dimensions are 7 in. W. X 15 in. H. X 18 in. D. The Topaz UPS was previously approved for use on the C-9 aircraft and is therefore only approved for use on large bodied aircraft. It produced radiated emissions, while operating on internal batteries, exceeding limits of the military standard for electromagnetic emissions and susceptibility. The Topaz UPS cannot be used on board any military aircraft while operating on internal batteries. Emissions levels while operating on 115 VAC/60 Hz aircraft power were within acceptable limits.

Venous Controller/Blood Pump Regulator

The Venous Controller (referred to as a "bladder box") is a locally fabricated device that holds the venous reservoir (bladder). The bladder box is plugged into 115 VAC/60 Hz power. Power is directed through a microswitch to the roller pump. It is imperative the pump be plugged into the receptacle in the bladder box and not directly into a 115 VAC/60 Hz outlet, otherwise there will be no servo control of the pump output. When the bladder is distended the switch head is depressed, and current flows to the pump. Conversely when the bladder empties the switch circuit is broken and power to the pump is interrupted (4). The bladder box weighs 3 lbs.

Neonatal/Pediatric ECMO Transport Gurney, Model WHMC-96

The gurney weighed 210 lbs empty, 742 lbs loaded (equipment only) with dimensions of 20 in. W. X 40 in. H. X 72 in. L. The gurney can accommodate a 20" X 40" plexiglas bassinet for neonates and infants, or a 20" X 72" mattress pad for larger patients secured to the patient platform. Other specifications are listed in attachment 1. Throughout this report, the term gurney refers to the WHMC-96 Neonatal/Pediatric ECMO Transport Gurney. The components of the EUT are secured underneath the patient platform on the left side of the gurney. The compressed gas cylinder mounting compartments accommodate 1 standard size Q cylinder containing oxygen, 1 standard size Q cylinder containing air, and 1 large size Q cylinder containing carbogen. The compressed gas cylinder mounting compartments are secured underneath the patient platform on the right side of the gurney. The left side of the gurney is designated as the head of the gurney, and the right side is designated as the foot.

Due to the EUT's size and weight it will only be approved for large bodied USAF aircraft. In addition, the Topaz UPS which provides battery power during ground transportation is only approved for use on large bodied aircraft.

PROCEDURES

Test methods and performance criteria were derived from nationally recognized performance guidelines (5, 6), various military standards (7-12), and manufacturer's literature (13-15). The Aeromedical Research Procedures Guide describes additional safety and human interface issues to be considered during equipment testing (16). A test setup and performance check were developed specific to this EUT to verify its proper functioning under various testing conditions. Unless otherwise noted, all testing is conducted and monitored by Aeromedical Research personnel assigned to the Flight Stress Protection Division, Human Effectiveness Directorate, Air Force Research Laboratory, Brooks AFB, Texas.

The EUT was subjected to various laboratory and inflight tests to observe and evaluate its performance under anticipated operational conditions.

1. Initial Inspection

2. Vibration

3. Electromagnetic Interference (EMI)

4. Thermal/Humidity Environmental Conditions, encompassing:

    a. Hot Operation

    b. Cold Operation

    c. Humidity Operation

5. Hypobaric Conditions

    a. Cabin Pressure/Altitude

    b. Rapid Decompression to Ambient Pressure

6. Airborne Performance

INITIAL INSPECTION AND TEST PREPARATION

a. The EUT was inspected for quality of workmanship, production techniques and pre-existing damage.

b. The EUT was checked to ensure it met safety requirements and operating characteristics established in National Fire Protection Agency (NFPA) 99 (5); AFI 41-203, Electrical Shock Hazards (8); and AFI 41-201, Equipment Management in Hospitals (7). Ground resistance and leakage current measurements were made at 115 VAC/60 Hz.

c. The EUT was examined to ensure it met basic requirements for human factors design as outlined in MIL-STD 1472 (12).

d. A test setup and performance check were developed to evaluate the EUT's operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

TEST SETUP

The test setups for individual components are listed in their respective technical reports.

PERFORMANCE CHECK

The performance checks for individual components are listed in their respective technical reports.

VIBRATION

Vibration testing is critical to determine "the resistance of equipment to vibrational stresses expected in its shipment and application environments" (11). Testing was conducted using a calibrated Unholtz-Dickie Vibration System, controller model UD-VWIN and shaker model R16W. This testing involved a set of operational tests performed along each of three axes - X, Y, and Z. The EUT components that underwent vibration testing included the CDI, 3M Health Care CDI 400 Extracorporeal Blood Gas Monitoring System; Seabrook Model SMS-3000 ECMO-Temp Blood Warming Unit; Stöckert Shiley Multiflow Roller Pump Module 10H Series, Model 10-10-00. Each of these components were tested individually since the transport gurney had not yet been developed. Components were individually secured directly to the vibration system adapter/mounting plate (Figure 2). Once the transport gurney was fabricated the EUT components listed in the description, including the compressed gas cylinders, were positioned on it for vibration testing. Since the vibration system at Brooks AFB was not large enough to accept the EUT, a calibrated Ling Electronics B335 Vibration System at SA-ALC/NWCP, Kelly AFB was used. All EUT components were secured within the gurney. The gurney was positioned on the vibration system (Figure 3) with two cargo tie-down straps and two C-9 type D-Rings. The casters were locked in position with the caster locking mechanism. One D-ring was secured to the floor track located at the foot of the gurney. The other D-ring was secured to the floor track located at the head of the gurney. A cargo tie-down strap was routed from the D-ring through the gurney securing handles and secured to the same D-ring. This was done at the head and foot of the gurney. This tie down method secured the gurney and prevented unsafe movement during vibration testing.

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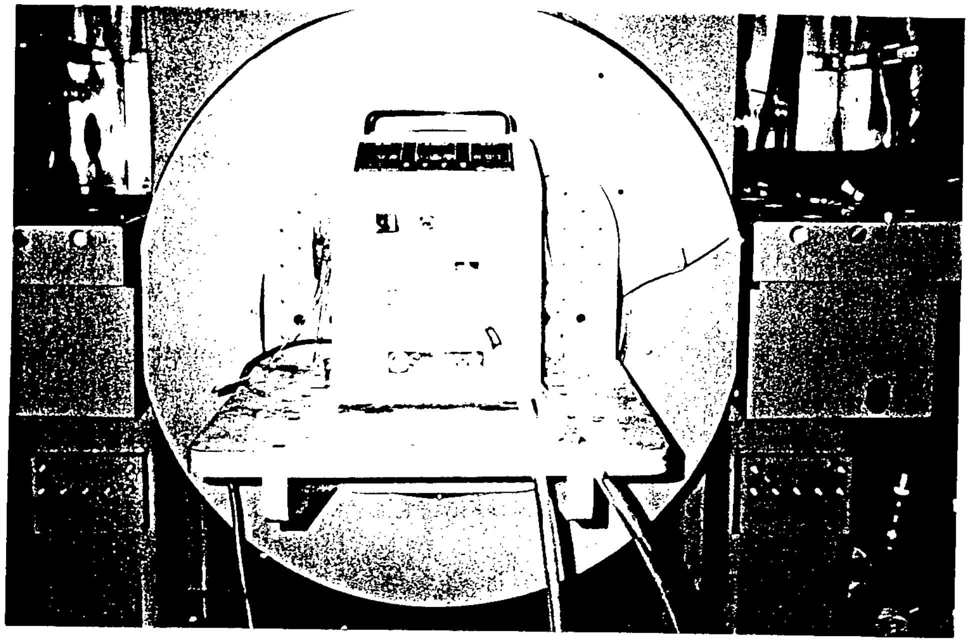


Figure 2. EUT Component Mounted On Vibration Table

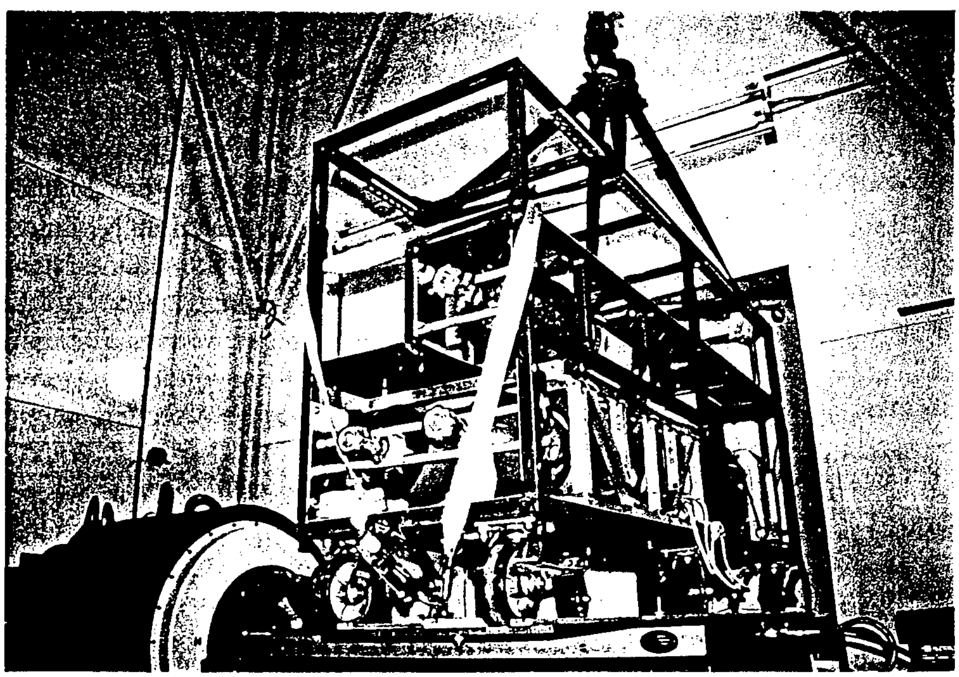
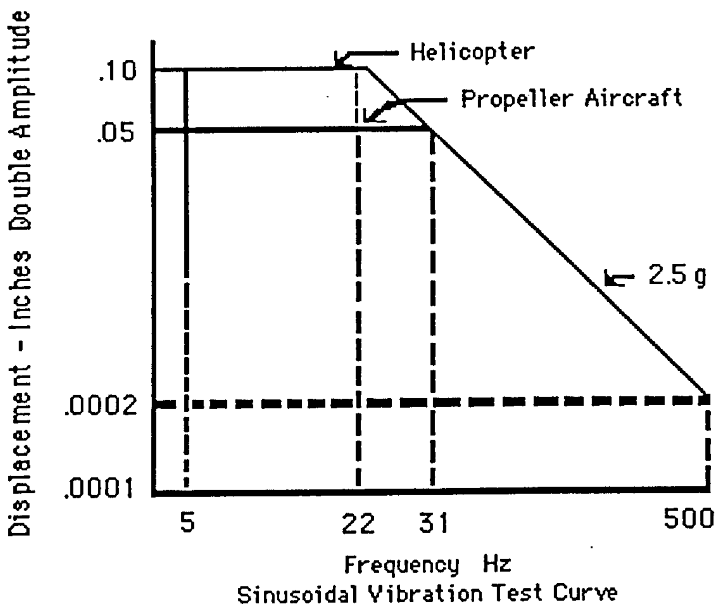


Figure 3. EUT Mounted On Vibration Table

All items were subjected to vibration curves with similar intensities and durations as those derived from MIL-STD-810E, Category 10, Figures 514.4-16 and 514.4-17 (Figure 4).



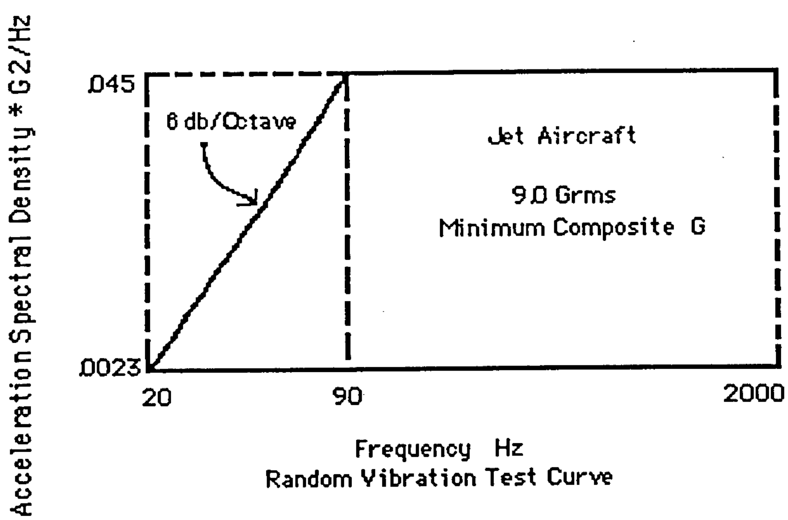


Figure 4. MIL-STD-810E, Category 10, figures 514.4-16 and 514.4-17

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility testing is a primary concern on USAF aeromedical evacuation aircraft. Safety is the driving factor in assessing the effects of excessive electromagnetic emissions, a source of potential influence on aircraft navigation and communications equipment. Medical devices may be susceptible to fields generated by aircraft equipment and malfunction in their presence. The EUT components tested for electromagnetic compatibility included the CDI, 3M Health Care CDI 400 Extracorporeal Blood Gas Monitoring System; Seabrook Model SMS-3000 ECMO-Temp Blood Warming Unit; and Stöckert Shiley Multiflow Roller Pump Module 10H Series, Model 10-10-00. Each of these components were tested individually.

The EUT components were evaluated for compliance with MIL-STD-461D and MIL-STD-462D (9,10). ASC/ENAI engineers at Wright-Patterson AFB evaluated the electromagnetic compatibility data and determined the airworthiness of the medical device. Specific tests conducted were as follows:

a. Radiated Emissions (RE-102), "Radiated Emissions, Electric Field, 10 kHz to 18 GHz.": For Air Force aircraft applications, radiated emissions were tested in a narrower range of frequencies from 2 MHz - 1 GHz. This test measured the amount of EMI emitted by the equipment during operation. It verifies the device's potential to affect other equipment susceptible to electromagnetic emissions (i.e., aircraft navigation and communications equipment).

b. Conducted Emissions (CE-102), "Conducted Emissions, Power Leads, 10 kHz to 10 MHz.": For Air Force aircraft applications, conducted emissions were tested throughout the entire band of 10 kHz - 10 MHz. This test measured emissions generated by the medical device along its power supply lines. It was performed to assess the device's potential to affect other items connected to the same power source, particularly aircraft systems.

c. Radiated Susceptibility (RS-103), "Radiated Susceptibility, Electric Field, 10 kHz to 40 GHz.": For Air Force aircraft applications, radiated susceptibility was tested in a narrower frequency range from 30 MHz - 12.4 GHz at the following field strength levels: 20 V/M below 1 GHz and 60 V/M above 1 GHz (MIL-STD-461D field strength values from Table IV, Category Aircraft Internal). This test evaluated the device's resistance to predefined levels of EMI generated by antennas both internal and external to the aircraft.

d. Conducted Susceptibility (CS-101), "Conducted Susceptibility, Power Leads, 30 Hz to 50 kHz.": For Air Force aeromedical aircraft applications, conducted susceptibility was tested throughout the entire frequency band, from 30 Hz to 50 kHz. This test evaluated the EUT components' ability to "withstand ripple voltages associated with allowable distortion of power source voltage wave forms."

e. Conducted Susceptibility (CS-114), "Conducted Susceptibility, Bulk Cable Injection, 10 kHz to 400 MHz.": For Air Force aeromedical aircraft applications conducted susceptibility was tested throughout the frequency band from 10 kHz to 200 MHz. This test determined whether "simulated currents that will be developed on platform cabling from electromagnetic fields generated by antenna transmission would affect the equipment under test."

f. Conducted Susceptibility (CS-115), "Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation": This test was performed to ensure the EUT components could withstand the "fast rise and fall time that may be present due to platform switching operations and external transient environments such as lightning and electromagnetic pulse."

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

Extreme temperature and humidity testing determines if aeromedical equipment can be stored and operated during severe environmental conditions without experiencing physical damage or deterioration in performance (11). Extreme environmental conditions can have incapacitating effects on medical equipment including changes in material characteristics and material dimensions, overheating, changes in lubricant viscosity, changes in electronic components, and electronic or mechanical failures due to rapid water or frost formation.

Testing was conducted in the Air Force Research Laboratory's A-7 Environmental Chamber. The EUT components that underwent extreme temperature and humidity testing included the CDI, 3M Health Care CDI 400 Extracorporeal Blood Gas Monitoring System; Seabrook Model SMS-3000 ECMO-Temp Blood Warming Unit; and Stöckert Shiley Multiflow Roller Pump Module 10H Series, Model 10-10-00.

During environmental testing the components were monitored continuously, and a performance check was conducted every 15 minutes. Environmental tests included:

a. Humidity: 94 ± 4% RH, 85°F ± 3.6°F (29.5°C ± 2°C) for 4 hours

b. Hot Temp Operation: 120°F ± 3.6°F (49°C ± 2°C) for 2 hours

c. Modified Hot Temp Operation: 85°F ± 3.6°F (29.5°C ± 2°C) for 2 hours

d. Cold Temp Operation: 32°F ± 7.2°F (0°C ± 4°C) for 2 hours

The Hot and Cold Temperature Storage tests were not done because the EUT will not be subjected to storage. The EUT will accompany the ECMO from Lackland AFB to the medical treatment facility where the patient is located.

HYPOBARIC CONDITIONS

Cabin Pressure/Altitude:

Altitude testing is critical for aeromedical evacuation equipment due to potential effects of barometric pressure changes on the equipment. A majority of the aircraft characterized as opportune aircraft available for use in aeromedical evacuation, pressurize their cabin atmosphere to barometric pressures equivalent to 8,000-10,000 ft above sea level. The differences in pressures affect the operation of some medical equipment. Altitude testing consisted of operating the EUT while ascending from ground level to 10,000 ft, stopping at 2,000 ft increments for performance checks, then descending back to ground level at 5,000 ft/min with a stop at 2,000 ft for performance checks.

Rapid Decompression Testing:

A rapid decompression (RD) is the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressure. It is important to assess medical equipment function during and after RD so as not to endanger the patient, personnel, or the aircraft. The EUT operated inside the rapid decompression test chamber as the chamber was depressurized to an equivalent of 8,000 ft. Then the chamber altitude was brought to 40,000 ft over a period of 60 seconds, held at 40,000 ft for a few minutes, and then returned to ground level at a rate of 10,000-12,000 ft/min. The test was repeated twice more; once for a 7-second RD and once for a 1-second RD. The EUT was monitored throughout the series of decompressions; performance checks were conducted each time the unit returned to ground level.

AIRBORNE PERFORMANCE

Airborne performance evaluations are a cost-effective and invaluable means of validating clinical and operational suitability under actual operating conditions. By carefully evaluating medical equipment items in their proposed operational environment, Aeromedical Research demonstrates all pertinent patient care issues are adequately addressed by the test protocols. Safe and reliable operation is the primary goal of the inflight evaluation and forms the basis for subsequent recommendations to the users.

This phase of testing was conducted by qualified aeromedical crew members (AECMs) from Aeromedical Research on C-9 and C-141 aeromedical evacuation missions. The EUT was positioned and secured to the neonatal/pediatric ECMO transport gurney and evaluated. Human factors characteristics, securing methods, setup/tear down times and securing locations were also evaluated. Feedback from ECMO team members, and other AECMs participating in delivery of patient care was obtained concerning EUT human factor considerations.

EVALUATION RESULTS

INITIAL INSPECTION

Initial inspection revealed no manufacturing defects on any of the EUT's components. Each component performed to the manufacturer's specification. Electrical safety test results showed all parameters to be within referenced guideline limits.

VIBRATION

The EUT's components operated within expected parameters during individual vibration tests. The gurney did not incur any degradation during vibration testing. The EUT components including the compressed gas cylinders remained secure. The tie down method used to secure the gurney prevented movement in an unsafe manner during vibration testing. This tie-down method is considered adequate.

ELECTROMAGNETIC COMPATIBILITY

The following is a summary of electromagnetic compatibility testing conducted on the components of the Neonatal/Pediatric ECMO Transport System, Model WHMC-96:

<u>CDI, 3M Health Care CDI 400 Extracorporeal Blood Gas Monitoring System</u>

The CDI 400 had excessive radiated emissions in the HF, VHF FM/AM, Localizer, and Marker Beacon bands limits when operating from 115 VAC / 60 Hz aircraft power or internal battery. WL/AASW modified the CDI 400 by improving the container shielding. The shield was improved by eliminating gaps in the shield and by reducing the gap between the front and the back container assemblies. This resulted in a 20dB reduction in radiated emissions. The shielding consisted of using Scotch™3M Type 1245 copper tape (nomenclature: embossed, copper foil, with acrylic pressure sensitive adhesive, flame retardant). Once the container was disassembled, the tape was secured to each half of the container. ASC/ENAI, Wright-Patterson AFB certified the modified CDI 400 for operation during all phases of flight on all Air Force aircraft while operating from 115 VAC / 60 Hz & battery power. All other CDI 400 Monitors are <u>not</u> certified for use aboard aircraft below 10,000 feet above ground level (AGL), as their emissions exceed the limits of MIL-STD-461D.

<u>Seabrook Model SMS-3000 ECMO-Temp Blood Warming Unit</u>

The SMS-3000 had radiated emissions in excess of MIL-STD-461D limits when plugged directly into 115 VAC / 60 Hz aircraft power. However, when plugged into a modified Tripplite® Isobar Model IB-4 noise filter/transient voltage surge suppresser the unit's radiated emissions did not exceed the MIL-STD-461D limits. ASC/ENAI, Wright-Patterson AFB certified the EUT for use in aeromedical evacuation system only on large-bodied U.S. Air Force aircraft while plugged into a modified Tripplite® Isobar Model IB-4, and operating from 115 VAC / 60 Hz power. See Appendix II for modification procedures.

Stöckert Shiley Multiflow Roller Pump Module, 10H Series, Model 10-10-00

The Roller Pump had conducted emissions in excess of MIL-STD-461D CE102 limits when plugged directly into 115 VAC / 60 Hz aircraft power. It was then plugged into a Tripplite® Isobar Model IB-4 noise filter/transient voltage surge suppresser. It failed CE102 with the flowrate set at 6 LPM. The test was repeated, but the Roller Pump still failed CE102 when the flowrate was reduced to 5.82 LPM. WL/AAWS investigatived various Electromagnetic Interference (EMI) modifications to the Roller Pump, but were unable to lower the emissions. The EMI modifications were removed from the Roller Pump, and investigative EMI fixes were done on the Tripplite® Isobar Model IB-4. With the Roller Pump connected to the modified surge suppresser, it still continued to fail CE102 with the flowrate set at 6 LPM. The flow rate was decreased in an attempt to pass CE102. Conducted emissions in excess of MIL-STD-461D limits were not produced at a flowrate of 5.82 LPM. The ECMO director was notified that the greatest flowrate possible to pass CE102 was 5.82 LPM. The ECMO director stated that flowrate was acceptable because the roller pump could still accommodate a 60 kg, adult size ECMO patient. The flowrate was left at 5.82 LPM for the duration of testing, and operated within expected parameters during testing. ASC/ENAI, Wright-Patterson AFB certified the Roller Pump for use during all phases of flight on all U.S. Air Force aircraft while plugged into a Tripplite® Isobar Model IB-4, and operating from 115 VAC / 60 Hz power. See Appendix II for modification procedures.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

The Stöckert Shiley Multiflow Roller Pump Module and CDI 400 Extracorporeal Blood Gas Monitoring System operated within expected parameters during hot, cold, and humidity operation testing. The Seabrook Model SMS-3000 ECMO-Temp Blood Warming Unit operated satisfactorily only during cold and humidity operation testing. During the hot operation test, it operated in excess of 10% above the preset water temperature. Therefore, modified hot operation tests at 35.0°C (95°F), 32.2°C (90°F), and 29.5°C (85°F) were conducted. The SMS-3000 operated in excess of 10% above the preset water temperature during the 35.0°C and 32.2°C hot operation tests. During the 29.5°C hot operation test, it operated within 10% of baseline readings.

HYPOBARIC CONDITIONS

Cabin Pressure/Altitude: The EUT's components operated within expected parameters during hypobaric testing.

Rapid Decompression: The EUT's components operated within expected parameters following each decompression.

AIRBORNE PERFORMANCE

The inflight evaluation of the EUT was performed on C-9 and C-141 aeromedical evacuation missions. ECMO team members headed by Major (Dr.) Beihl were present during the airborne performance evaluations. The following items accompanied the ECMO team: one ECMO support cart designed to secure two "Q" Cylinders and one "D" Cylinder; two Unicell ECMO transport-storage cabinets; one blue ECMO transport box; two transport suitcases; one S-Scort portable suction for ground transportation use; and miscellaneous supply items deemed necessary by the ECMO team. These items were tied-down by the aeromedical crew and were not part of the EUT evaluation.

Each Medical Crew Director (MCD) and Charge Medical Technician (CMT) were consulted to determine the placement of the EUT on the aircraft. The AECMs assigned to each mission were briefed on unloading/loading of the EUT. One AECM supervised the movement of the EUT. This AECM was the CMT from the aeromedical evacuation aircraft. It is imperative that everyone involved with the lifting/rolling of the EUT understand what commands/direction will be given. The EUT was removed from the ambulance by eight individuals (four on each side of the gurney) (Figure 5).

Figure 5. EUT Being Removed From Ambulance

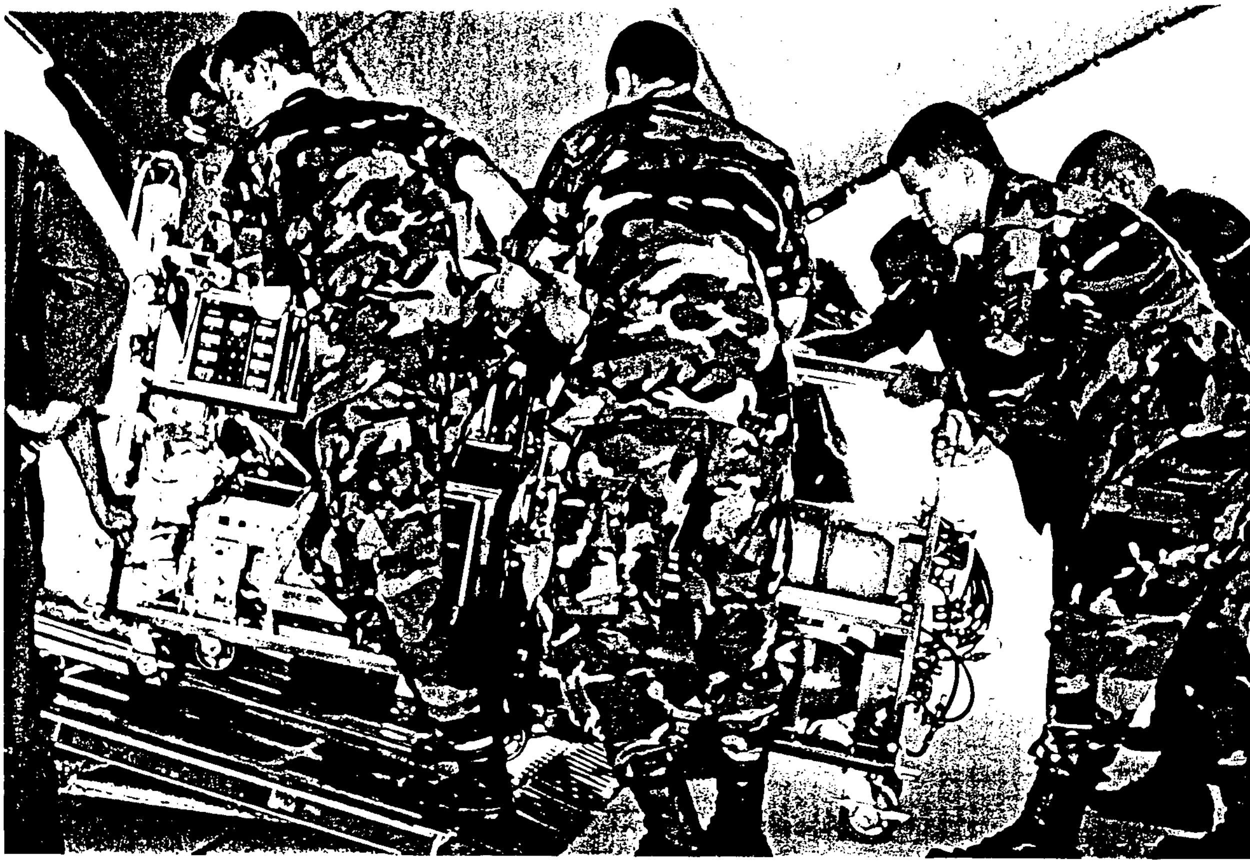


Figure 6. EUT Being Rolled Up C-141 Ramp

The EUT was rolled up the C-141 and C-9 ramps respectively using seven individuals (three on each side and one at the bottom end) (Figures 6 & 7). The gurney was secured as follows:

On the C-141 aircraft, the gurney was positioned between the two center seat tracks located across from flight station 1080 (Figure 8). The centerline stanchions were not installed at this location. The foot of the gurney was positioned forward and the head was positioned aft. The gurney was shored with 3/8" thick 1 ft X 1 ft plywood planks under the casters (Figure 9). Each plank was placed next to each caster at the end of the gurney, then the gurney was rolled onto the board. Shoring is defined as, "boards or planking placed on cargo floor to spread the load over a larger area, or prevent damage" (17). We ensured that all of the EUT components and loose accessories were secured within the gurney. The gurney was secured with two cargo tie-down straps and four D-Rings. The casters were locked in position with the caster locking mechanism. One D-ring was secured to each seat track approximately 1 foot forward of gurney. One D-ring was secured to each seat track approximately 1 foot aft of gurney. A cargo tie-down strap was secured to one D-ring, routed through the gurney securing handles at the head of the gurney, and secured to the other D-ring. This was also done at the foot of the gurney. This tie down method secured the gurney and prevented movement during flight.

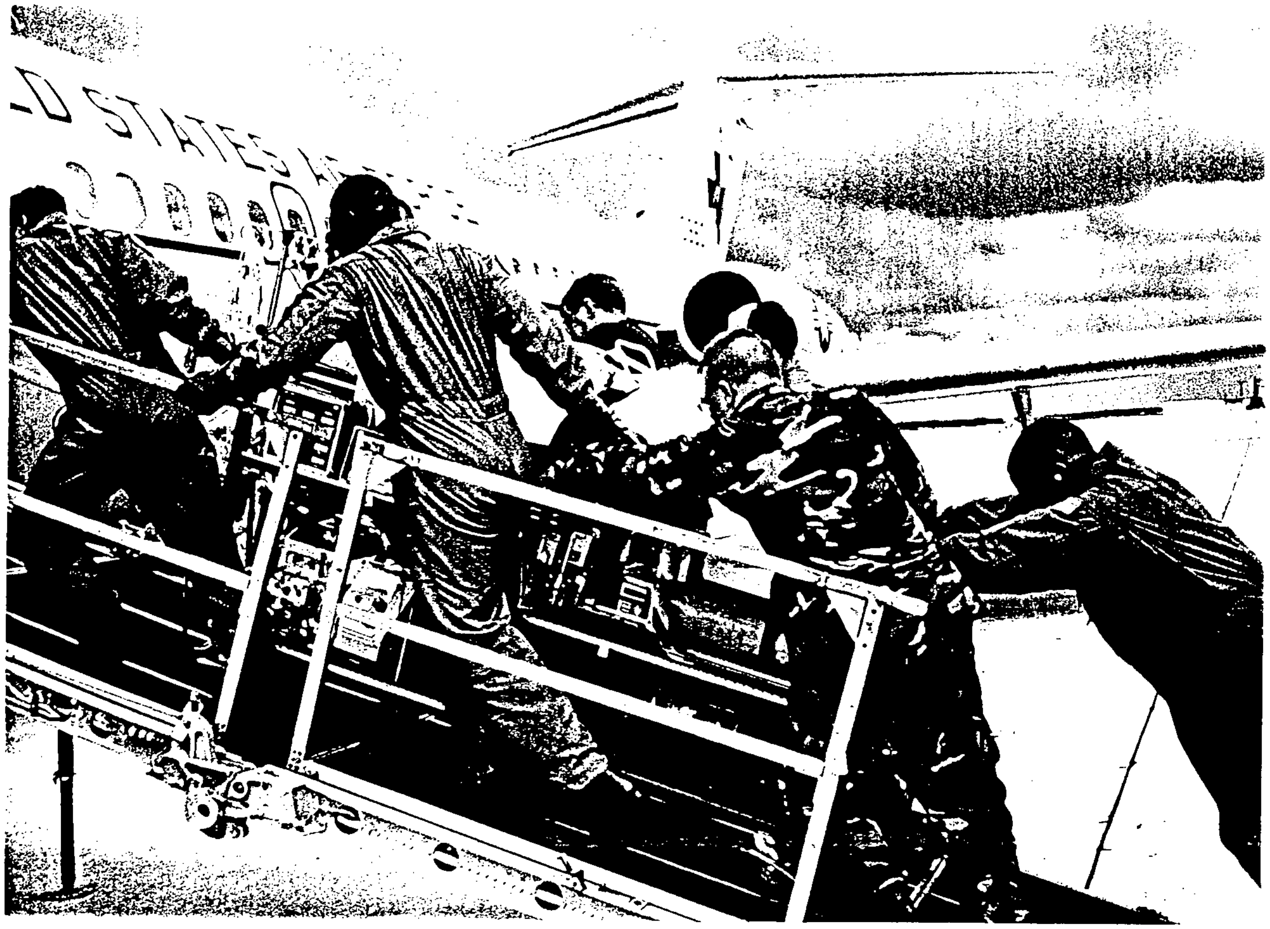


Figure 7. EUT Being Rolled Up C-9 Ramp

This technique is consistent with the following statement from the C141 technical manual: "Cargo must be tied down in such a manner that the load will be prevented from moving" (17). The Topaz UPS was plugged into the electrical frequency converter. Research personnel and ECMO team members were seated adjacent to the EUT on side facing seats.

The C-9 interior was arranged in a 3 Tier/34 Seat configuration. The gurney was positioned on the left side of the aircraft at position TL1 over the inboard seat track (Figure 10). The Support Stanchion and Combination Utility Stanchion were in the litter configuration. The stanchions prevented the gurney from being secured between the two seat tracks. The foot of the gurney was positioned forward and the head was positioned aft. The gurney was secured with two cargo tie-down straps and two D-Rings. The casters were locked in position with the caster locking mechanism. One D-ring was secured to the seat track approximately 1 foot forward of gurney. One D-ring was secured to the seat track approximately 1 foot aft of gurney. A cargo tie-down strap was secured the D-ring, routed through the gurney securing handles at the head of the gurney, and secured to the same D-ring. This was also done at the foot of the gurney. This tie down method secured the gurney and prevented movement during flight. No boards or planks were used to shore the C-9 floor.

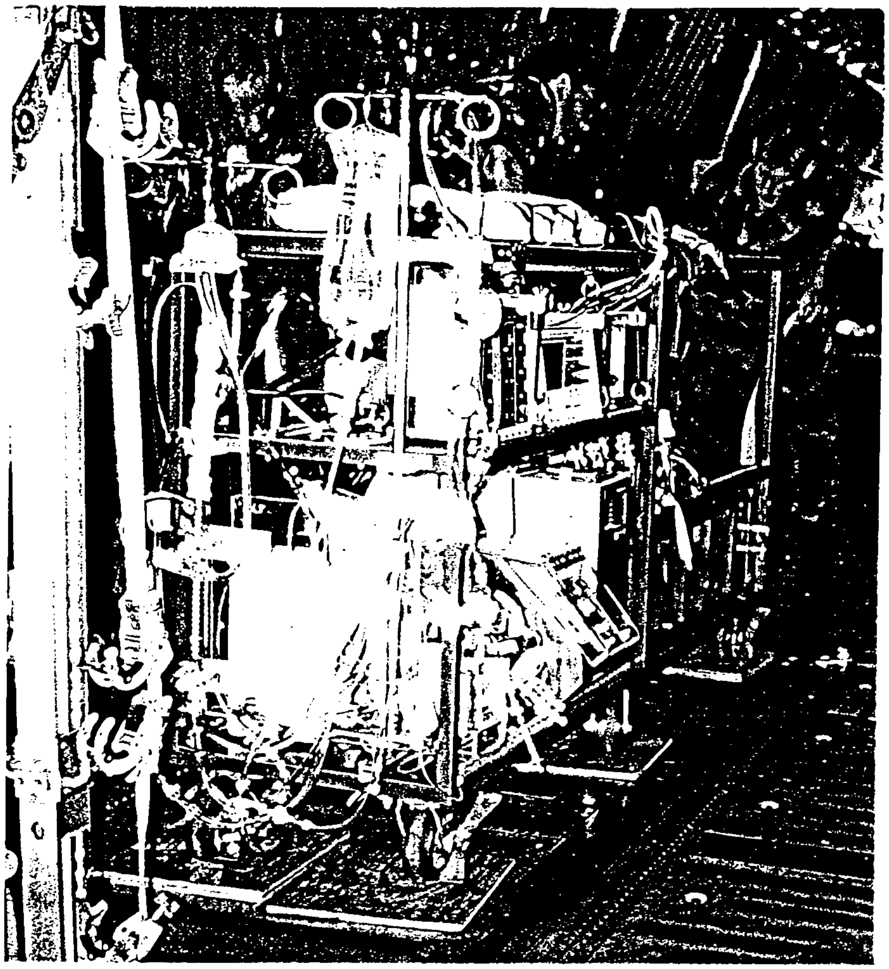


Figure 8. EUT Location on the C-141B Aircraft

According to the McDonnell-Douglas Field Service Representatives at Scott AFB, the C-9 floor did not require shoring to distribute the weight. On the C-9 aircraft, we also ensured all of the EUT components and loose accessories were secured within the gurney. After the flight, the aircraft floor did not appear to be damaged by any of the casters. However, we recommend that plywood shoring be used during all ECMO transports on all aircraft. This practice will allow for the gurney weight to be distributed over a greater surface. Research personnel and ECMO team members were seated adjacent to the EUT.

When electrical power was switched from power cart/auxiliary power unit (APU) to aircraft power, the EUT continued to operate inspite of the momentary power interruption that commonly occurs. The clinical acceptability of this system during aeromedical transport was based on the extensive clinical knowledge and experience of the ECMO team. Capped/uncapped Q cylinders secured in the mounting compartments of the gurney are approved for inflight use. Evaluation confirmed that the EUT would operate within expected parameters during all phases of flight. We see no reason to limit securing of the gurney with the head aft and the foot forward. On ECMO transports, AECMs or loadmasters should be responsible for the installation of D-Rings and cargo tiedown straps.

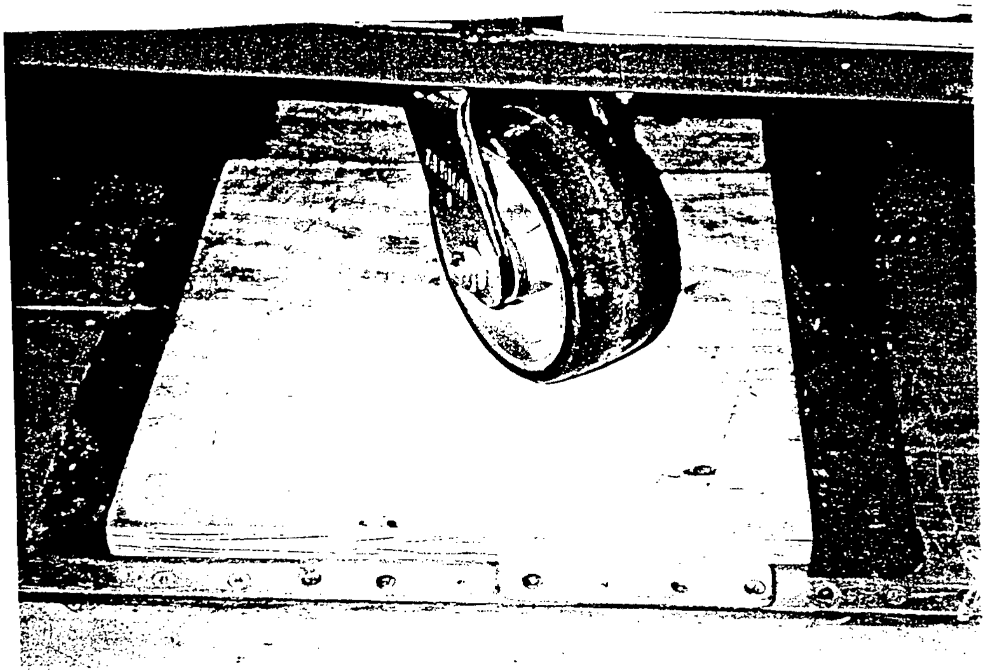


Figure 9. EUT Positioned On Plywood Shoring

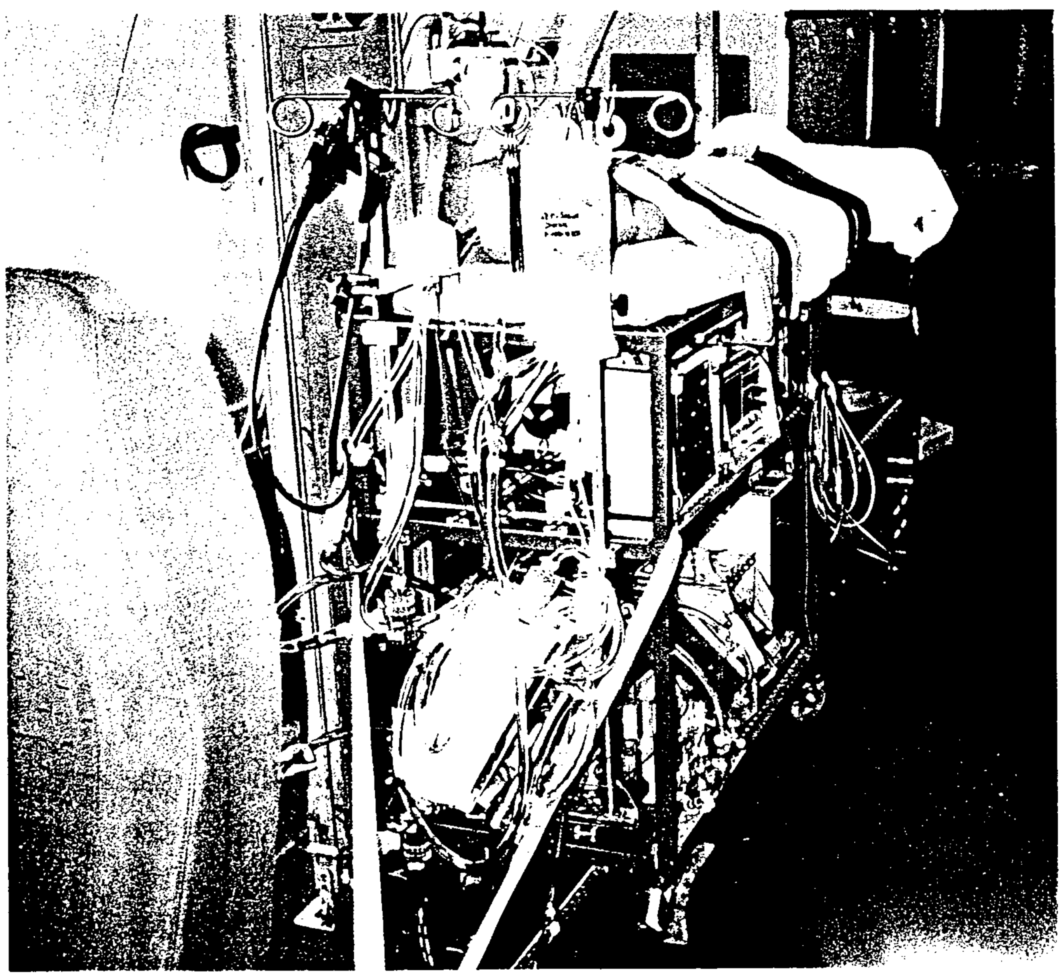


Figure 10. EUT Location on the C-9A Aircraft

SUMMARY

Aeromedical Research found the Neonatal/Pediatric ECMO Transport System, Model WHMC-96 conditionally acceptable for use on large bodied U.S. Air Force aeromedical evacuation aircraft. Due to the size and weight of this system, it is only approved for large bodied aircraft such as the C-130, C-141, C-9, etc. The components of the EUT are approved for use during all phases of flight unless otherwise specified below. Plywood planks (1 ft x 1 ft x 3/8") were provided to the ECMO team for the purpose of shoring the aircraft floor. We recommend that plywood shoring be used during all ECMO transports on all aircraft. Please note the recommendations and operational restrictions listed below.

1. CDI, 3M Health Care CDI 400 (modified) Extracorporeal Blood Gas Monitoring System
The modified CDI 400, Serial No. 5631 operated within expected parameters when subjected to vibration, electromagnetic Interference (EMI), environmental extremes, simulated cabin altitudes, and did not produce a hazard to patient or crew during rapid decompression. It is acceptable for use during all phases of flight on all Air Force aircraft while operating from 115 VAC / 60 Hz or battery power.

2. CDI, 3M Health Care CDI 400 (unmodified) Extracorporeal Blood Gas Monitoring System
All unmodified CDI 400 Extracorporeal Blood Gas Monitoring Systems are conditionally acceptable for use, and may only be used inflight. Unmodified CDI 400 Monitors are not certified for use below 10,000 feet AGL, as their emissions exceed the limits of MIL-STD-461D. This means that an unmodified CDI 400 must be turned off during takeoff and landing. The CDI 400 Monitor may be shut off without loss of the most recent calibration data (13). It may be used inflight on all Air Force aircraft while operating from 115 VAC / 60 Hz or battery power only.

3. Seabrook Model SMS-3000 ECMO-Temp Blood Warming Unit
Its operation was within expected parameters when subjected to vibration, electromagnetic interference (EMI), cold and humid environmental extremes, simulated cabin altitudes, and did not produce a hazard to patient or crew during rapid decompression. Since the SMS-3000 operated within expected parameters during the airborne performance phases of testing it is deemed conditionally acceptable for use. The following requirements apply:

a. Must be plugged into a modified Tripplite Isobar Model IB-4 noise filter and transient voltage surge suppresser to reduce EMI below limits

b. The setpoint temperature must be adjusted if the ambient temperature at the enplaning or deplaning station exceeds 29.5°C (85°F)

4. Stöckert Shiley Multiflow Roller Pump Module, 10H Series, Model 10-10-00

Its operation was within expected parameters when subjected to vibration, cold and humid environmental extremes, simulated cabin altitudes, and did not produce a hazard to patient or crew during rapid decompression. The maximum flowrate authorized is 5.82 LPM since the pump exceeded EMI limits when the flowrate was set above 5.82 LPM. The pump is conditionally acceptable for use, however, the following requirements apply:

a. Plugged-in as follows:

1) Plugged-in in series into the Venous Controller/Blood Pump Regulator ("bladder box"), then the modified Tripplite Isobar, then the Topaz UPS, then into 115 VAC/60 Hz aircraft power

Example:
Roller Pump → Bladder box → Modified Tripplite Isobar → Topaz UPS → 115 VAC/60 Hz power

2) Must be plugged into a modified Tripplite® Isobar Model IB-4 noise filter and transient voltage surge suppresser to reduce EMI below limits

3) Must be plugged into a Topaz UPS to provide battery support during ground transport
Note: The Topaz UPS is only approved for large bodied aircraft

b. Flowrate set at 5.82 LPM or less.

5. Neonatal/Pediatric ECMO Transport Gurney, Model WHMC-96

a. The components of the EUT are secured to the gurney. At the users discretion, medical equipment previously found acceptable for use for aeromedical evacuation may be used with the EUT.

b. All the components of the EUT are to be positioned, secured, set-up, and operated by ECMO team members at the hospital prior to arrival at the aircraft.

c. Loading: Use eight individuals (four on each side of the gurney) to unload gurney from the ambulance. Use seven individuals (three on each side and one at the bottom end) to roll up aircraft ramp.

d. Capped/uncapped Q cylinders secured in the mounting compartments are approved for inflight use on all large body USAF aircraft.

e. Use boards or planks for shoring aircraft floor.

f. The securing of the gurney should be done by AECMs or loadmasters.

g. Secure the gurney as follows:

1) C-141 or Other Cargo Aircraft

a) The procedure requires 4 D-rings, 2 cargo tie-down straps, and plywood planks or boards used for shoring the aircraft floor
b) According to load plan roll the gurney to the identified litter tier
c) At the discretion of the MCD/CMT and loadmaster the gurney may be placed between a centerline stanchion
d) The restraining cables must be removed if the gurney is to be positioned between a centerline stanchion
e) Position the gurney between two seat tracks
f) Prior to securing, place 1 ft x 1 ft 3/8" plywood planks next to each wheel
g) Roll gurney onto plywood planks
h) Engage the caster locking mechanism
i) Position and secure D-Rings (1 ea) to each seat track approximately 1 foot aft and 1 foot forward of gurney
j) Secure each end of the gurney with 1 cargo tiedown strap
k) At the head of the gurney, route one cargo tie-down strap from one D-ring through the gurney securing handles and secured to the other D-ring
l) At the foot of the gurney, route one cargo tie-down strap from one D-ring through the gurney securing handles and secured to the other D-ring
m) Plug the Topaz UPS into the electrical frequency converter

2) C-9 Aircraft With The Support Stanchion and Combination Utility Stanchion in the Stowed Position

a) The procedure requires 4 D-rings, 2 cargo tie-down straps, and plywood planks or boards used for shoring the aircraft floor
b) At the discretion of the MCD/CMT the gurney may be placed in this configuration
c) Determine what litter tier the gurney will be positioned
d) Stow the support stanchion and combination utility stanchion in the horizontal position
e) Position the gurney between the inboard and outboard seat tracks
f) Prior to securing, place 1 ft x 1 ft 3/8" plywood planks next to each wheel
g) Roll gurney onto plywood planks planks
h) Engage the caster locking mechanism
i) Position and secure D-Rings (1 ea) to each seat track approximately 1 foot aft and 1 foot forward of gurney
j) Secure each end of the gurney with 1 cargo tiedown strap
k) At the head of the gurney, route one cargo tie-down strap from one D-ring through the gurney securing handles and secured to the other D-ring
l) At the foot of the gurney, route one cargo tie-down strap from one D-ring through the gurney securing handles and secured to the other D-ring
m) Plug the Topaz UPS into 115 VAC/60 Hz aircraft power

3) C-9 Aircraft With The Support Stanchion And Combination Utility Stanchion In The Litter Configuration

a) The procedure requires 2 D-rings, 2 cargo tie-down straps, and plywood planks or boards used for shoring the aircraft floor
b) At the discretion of the MCD/CMT the gurney may be placed in this configuration
c) According to load plan roll the gurney to the identified litter tier
d) Position the gurney over the inboard seat track
e) Prior to securing, place 1 ft x 1 ft 3/8" plywood planks next to each wheel
f) Roll gurney onto plywood planks
g) Position and secure D-Rings (1 ea) to each seat track approximately 1 foot aft and 1 foot forward of gurney
h) Secure each end of the gurney with 1 cargo tiedown strap
i) Engage the caster locking mechanism
j) At the head of the gurney, route one cargo tie-down strap from one D-ring through the gurney securing handles and secured to the same D-ring
k) At the foot of the gurney, route one cargo tie-down strap from one D-ring through the gurney securing handles and secured to the other D-ring
l) Plug the Topaz UPS into 115 VAC/60 Hz aircraft power

6. Required support equipment supplied by the aeromedical evacuation squadron (AES):

a. One Timeter Aridyne medical air compressor, model 3500 or compressed air cylinders

b. One electrical frequency converter is required on cargo aircraft

7. Required support equipment supplied by WHMC:

a. ECMO support cart (1 ea), designed to secure two "Q" Cylinders and one "D" Cylinder, see Appendix III for approval letter

b. Unicell ECMO transport storage cabinet (2 ea)

c. Blue ECMO transport box (1 ea)

d. Transport suitcases (2 ea)

e. S-Scort portable suction (1 ea) for ground transportation use

d. Miscellaneous supply items deemed necessary by the ECMO team

REFERENCES

1. AFRL-HE-BR-TR-1998-0020, Testing And Evaluation Of The CDI, 3M Healthcare CDI 400 Extracorporeal Blood Gas Monitoring System.

2. AFRL-HE-BR-TR-1998-0019, Testing And Evaluation Of The Seabrook Medical Systems, Inc., ECMO-Temp Blood Warming Unit, Model SMS-3000.

3. AFRL-HE-BR-TR-1998-0080, Testing And Evaluation Of The Stockert Shiley Multiflow Roller Pump Module.

4. Wilford Hall USAF Medical Center (WHMC) ECMO Specialist Training Manual.

5. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code.

6. Emergency Care Research Institute (ECRI), Health Devices

7. AFI 41-201, Equipment Management in Hospitals.

8. AFI 41-203, Electrical Shock Hazards.

9. MIL-STD 461D, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference.

10. MIL-STD-462 D, Measurement of EMI Characteristics.

11. MIL-STD 810E, Environmental Test Methods and Engineering Guidelines.

12. MIL-STD 1472, Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.

13. CDI, 3M Health Care, CDI™ 400 Extracorporeal Blood Gas Monitoring System, Operations and Service Manual.

14. Seabrook Medical Systems, Inc., Seabrook Model SMS-3000, Operations & Service Manual.

15. Stöckert Shiley Multiflow Roller Pump Module Instructions For Use Manual.

16. Aeromedical Research Procedures Guide, Internal Operating Instruction, Systems Research Branch, Armstrong Laboratory.

17. TO 1C-141B-9, Technical Manual, Loading Instructions, USAF Series C-141B Aircraft

APPENDIX I
NEONATAL/PEDIATRIC ECMO TRANSPORT SYSTEM, MODEL WHMC-96 SPECIFICATIONS

Dimensions

Neonatal/Pediatric ECMO Transport Gurney, Model WHMC-96

Length	72 inches
Width	20 inches
Height	40 inches

Weight

CDI 400	16.3 lbs
Gurney (empty)	210 lbs
Gurney (loaded)	742 lbs
Misc. ECMO equipment	8.2 lbs
Modified Tripplite® Isobar Model IB-4	1.5 lbs
Seabrook Model SMS-3000	28 lbs(wet)
Stöckert Shiley Multiflow Roller Pump	55 lbs
Topaz Uniterruptible Power Supply, Model 84126-01.	90 lbs
Venous Controller/Blood Pump Regulator	3 lbs
Q-Tank (reg. size, 36 lbs, 2 ea)	72 lbs
Q-Tank (large size, 58 lbs, 1 ea)	58 lbs

NOTE:
1. The square tubing used to construct gurney frame was steel 1" x 1" x 0.63, No. 4130, total tubing wt 96 lbs
2. If 1" x 1" x 0.63, No. 6063, square aluminum tubing was used the total gurney frame weight would be 72 lbs

Power Requirements

1. CDI 400
   a. 115 VAC/60 Hz using battery charger/AC adapter
   b. 12 volt, 6 amp-hour rechargeable battery
2. Seabrook Model SMS-3000
   a. 100 to 250 VAC/50 or 60 Hz, 320 watts, max.
   b. The Topaz UPS serves as the external battery
3. Stöckert Shiley Multiflow Roller Pump
   a. 100 to 250 VAC/50 or 60 Hz, 320 watts, max.
   b. The Topaz UPS serves as the external battery
4. Modified Tripplite® Isobar Model IB-4
5. Topaz Uniterruptible Power Supply, Model 84126-01
   a. 102-132 VAC/60 Hz
   b. Internal batteries, two 12V, 28 Amp-hour total, sealed gel cell, lead acid
   c. Output: 120 ± 3.5 VAC/60 ± 1 Hz, 1000 VA
6. Venous Controller/Blood Pump Regulator
   115 VAC/60 Hz, 3 amp fuse

APPENDIX II

MODIFICATION PROCEDURE FOR THE TRIPPLITE® ISOBAR, MODEL IB-4 NOISE FILTER AND TRANSIENT VOLTAGE SURGE SUPPRESSER

PURPOSE: To provides noise filter and transient voltage surge suppresser and reduce conducted emissions in excess of MIL-STD-461D for the following medical devices:

1. Seabrook Model SMS-3000 ECMO-Temp Blood Warming Unit
2. Stöckert Shiley Multiflow Roller Pump Module, 10H Series, Model 10-10-00, the Venous Controller/Blood Pump Regulator ("bladder box")

MODIFICATION PROCEDURES:

1. Remove the four screws from the end plate opposite the power cord.
2. Remove the end plate opposite the power cord.
3. Remove the bottom screw on the end plate holding the power cord.
4. Slide bottom half of unit to left and remove.
5. Turn unit upside down with power cord to the right.
6. Place the .033UFB 1600WVDC Type 715P Orange Drop Polypropylene Dipped Tubular Capacitor behind the blue capacitor on the left end on the PC board with the capacitor leads pointing toward the toroid in front of the blue capacitor.
7. Solder the left lead of the .033UFD capacitor to the left lead of the toroid.
8. Solder the left lead of the .033UFD capacitor to the right lead of the toroid.
9. Remove the left (white wire) connector from the power switch located next to the right end of the PC board.
10. Remove the center (black wire) connector from the power switch, and mark it "center" with masking tape.
11. Remove the right (black wire) connector from the power switch, and mark it "right with masking tape.
12. Remove the two screws on the top of the unit which are located between the power receptacles.
13. Lift the PC board upward and backwards.
14. Place the .047UFD 1600WVDC Type 715P Orange Drop Polypropylene Dipped Tubular Capacitor between the power switch and the circuit breaker with the capacitor leads pointing toward the power switch.
15. Replace the PC board in it's original position.
16. Replace the two screws on the top of the unit which are located between the power receptacles.
17. Replace the connectors on the power switch in their original positions.
18. Solder the left lead of the .047UFD capacitor to the left connector on the power switch.
19. Solder the right lead of the .047UFD capacitor to the right connector on the power switch.
20. Slide the bottom half of the unit on.
21. Replace the end plate opposite the power cord.
22. Replace the four screws in the end plate opposite the power cord.
23. Replace the two bottom screws on the end plate with the power cord.

APPENDIX III

DEPARTMENT OF THE AIR FORCE
ARMSTRONG LABORATORY (AFMC)
BROOKS AIR FORCE BASE, TEXAS

28 August 95

MEMORANDUM FOR: LtCmdr Jeffery T. Butler

FROM: Aeromedical Research
AL/CFTS
2504 Gillingham Dr. Suite 25
Brooks AFB TX 78235-5104

SUBJECT: Testing of two modified ECMO Carts

1. Modification and airworthiness testing of two Extra Corporeal Membrane Oxygenation (ECMO) Carts have been completed. These modified units were tested with oxygen bottles in place and found to be acceptable for use on USAF aeromedical evacuation aircraft. Modifications were as outlined below:

Cart #1:

-- Oxygen Cylinder Mounting Plate with associated support braces - Fabricated from 2024 aircraft aluminum and designed to secure three "Q" Cylinders

-- Side Braces - Fabricated from 2024 aluminum and designed to provide needed structural integrity

-- Incubator Hold Down Brackets - Constructed from 2024 aluminum and designed to secure the incubator to the top of the cart

-- Improved casters to ease transportation

Cart #2:

-- Oxygen Cylinder Mounting Plate with associated support braces - Fabricated from 2024 aircraft aluminum and designed to secure two "Q" cylinders and one "D" cylinder

-- Side Braces - Fabricated from 2024 aluminum and designed to provide needed structural integrity

-- Improved casters to ease transportation

2. These ECMO Carts successfully passed vibration testing however, as an extra measure of protection mini ratchet cargo straps can be secured to the legs of each cart and around the oxygen bottles.

3. We are pleased to have had the opportunity to work with you. Any questions can be directed to the principle investigator Mr. Edward Hade (210) 536-3847.

Jacqueline D. Hale

JACQUELINE D. HALE, Lt Col, USAF, NC
Chief, Aeromedical Research